

REMARKS

The Applicants appreciate the Examiner's thorough examination of the subject application. Applicants request reconsideration of the subject application based on the following remarks.

Claims 32-36, 38-44, and 52-53 are pending in the application. Claims 1-31, 37, and 45-51 have been cancelled. Applicants expressly reserve the right to pursue the subject matter of the cancelled claims in this or a subsequent application. Support for new claim 52 can be found at least in the specification as filed, on page 65. Claims 34, 36, and new claim 53 are dependent claims directed towards spinal cords. Support can be found at least in the claims as originally filed.

Claims 32-44, 46-47, and 50-51 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention of record. It is further alleged that the specification does not reasonably provide enablement for the treatment of diseases caused by injuries to nervous tissues or the spinal cord.

Applicants have amended claim 32 and dependent claims 33-36 to be directed towards traumatic or compression injuries to nervous tissues. Support can be found at least in the specification as originally filed, in Example 4, which demonstrates the effect of ginsenoside Rb₁ for the treatment of diseases caused by injuries to the spinal cord (a nervous tissue).

Example 4 demonstrates that anesthetized rats were subjected to spinal cord injury by compression loading. The vertebral arch was removed from the rats to expose the spinal cord and the spinal cord injury was prepared by directly loading 20 g of

compression for 20 min. Because the rats' weight is about 300 g, and 20 g of compression was applied, approximately 1/15 of the rats' weight was administered as the compression loading. This weight is comparable to 4 kg (~8.8 pounds) weight being loaded directly onto the exposed spinal cord of a human weighing 60 kg (~132.3 pounds).

The compression applied to the nervous tissues and spinal cord tissues resulted in the destruction of said tissues, and resulting neuroparalysis. Those of ordinary skill in the art are aware that the seriousness of these injuries are comparable to other models of neurotrauma, such as head injuries and brain injuries. Thus, Example 4 demonstrates a model of traumatic or compression injury to the nervous tissues.

When a saline solution was administered as a treatment, it was determined that the rat exhibited paraplegia in both hind limbs (Figure 8A). However, when a solution of ginsenoside Rb₁ was administered, the paraplegia of both hind limbs was significantly ameliorated (Figure 8B). Figure 8B demonstrates that the rat had the ability to stand up with the aid of a standing bar. Additionally, Figure 9 shows that the motor ability of the rats with spinal cord injuries was significantly ameliorated after administration of ginsenoside Rb₁.

Among neurotrauma, those of ordinary skill in the art are aware that spinal cord injuries are among the most difficult to treat. It is therefore determined that effective compounds for the treatment of serious spinal cord injuries can be expected to be effective on general neurotrauma, such as head injuries and peripheral nerve injuries.

Therefore, Applicants respectfully submit that the instant application provides sufficient enablement for the treatment of diseases caused by traumatic or compression injuries to nervous tissues, comprising the step of administering to a patient a therapeutically effective amount of a pharmaceutical composition comprising a therapeutic agent selected from ginsenoside Rb₁, its metabolites and salts thereof.

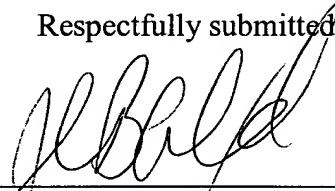
Applicants indicate that the rejection is thus obviated and respectfully request withdrawal of the rejection.

Claims 32-44, 46-47, and 50-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-12 of U.S. Patent No. 6,579,853 (U.S.S.N. 09/887,399).

A terminal disclaimer was filed on February 28, 2003, to disclaim any term for patents issuing in connection with the instant application extending beyond the expiration of U.S.S.N. 09/887,399, now issued as U.S. Patent No. 6,579,853. Thus, the rejection has been overcome.

The Examiner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

Respectfully submitted,



Date: March 7, 2005

John B. Alexander (Reg. No. 48,399)
EDWARDS & ANGELL, LLP
P. O. Box 55874
Boston, MA 02205
Tel: (617) 439-4444
Fax: (617) 439-4170